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K013783

510(k) Summary
for
AUTION MAX™ AX-4280 Urinalysis System

1. SPONSOR

International Remote Imaging Systems, Inc.
9162 Eton Avenue
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Date Prepared: November 12, 2001

2. DEVICE NAME

Proprietary Name: AUTION MAX AX-4280 Urinalysis System
Common/Usual Name: Urinalysis System
Classification Name: Automated Urinalysis System

3. PREDICATE DEVICES

- Clinitek Atlas Automated Urine Chemistry Analyzer, Bayer Corporation (K946183)
- Chemstrip® Super UA™ Automated Urine Analyzer, Boehringer Mannheim Corporation (K983510)

4. DEVICE DESCRIPTION

The AUTION MAX Urinalysis System consists of an Analyzer, Sampler, and accessories. ARKRAY also offers an external printer and hand-held Bar Code Reader for use with the AUTION MAX. The sample-handling capacity of the AUTION MAX can be expanded through the use of the Extensional Sampler. The

AUTION MAX Analyzer is designed for use with the AUTION Sticks 9EB multi-parameter test strips.

5. INTENDED USE

The AUTION MAX AX-4280 Urinalysis System (AUTION MAX) is an automated urine analyzer intended for the in vitro measurement of the following analytes: glucose (GLU), protein (PRO), bilirubin (BIL), urobilinogen (URO), pH, blood (BLD), ketones (KET), nitrite (NIT), leukocytes (LEU), specific gravity (SG), turbidity, and color. The AUTION MAX is intended for use only with the AUTION Sticks 9EB multi-parameter test strips.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The AUTION MAX is substantially equivalent to the Clinitek Atlas Automated Urine Chemistry Analyzer with Rack Sample Handler (Clinitek Atlas), manufactured by Bayer Corporation (K946183). The Clinitek Atlas is intended for use with the Clinitek® Atlas® Reagent Pack reagent strips. Both the proposed AUTION MAX and the Clinitek Atlas measure urine GLU, PRO, BIL, URO, pH, BLD, KET, NIT, LEU, SG, color, and clarity.

The AUTION MAX is also substantially equivalent to the Chemstrip® Super UA™ Automated Urine Analyzer (Chemstrip Super UA), manufactured by Boehringer Mannheim Corporation (K983510). The Chemstrip Super UA is intended for use with the Chemstrip® 10 S-UA urine test strips. The Chemstrip Super UA measures urine GLU, PRO, BIL, URO, pH, BLD, KET, NIT, LEU, and SG.

The proposed AUTION MAX Analyzer contains:

- Mechanical systems for handling the test strips, urine specimens, wash solution, and system waste
- Measurement units for reading the test strips and analyzing the physical properties of the urine
- Software control system for automation of Analyzer and Sampler operation, processing commands and information input by the user, displaying system and specimen information, and monitoring system functions

- RS-232C interface for exporting measurement results and urine specimen identification information

The AUTION MAX uses a rack system for urine specimen handling. The AUTION MAX Sampler automatically feeds sample racks to the Analyzer. The Sampler contains a Bar Code Reader for urine specimen identification.

The overall design of the predicate Clinitek Atlas and the Chemstrip Super UA is similar to that of the proposed AUTION MAX, with the exception that the urine specimens are transported to the Chemstrip Super UA analyzer using a turntable rather than a rack system.

The proposed AUTION MAX Analyzer uses reflectance spectroscopy for the measurement of the urine analytes GLU, PRO, BIL, URO, pH, BLD, KET, NIT, LEU, and urine color. Urine SG is determined using the refractive index method, and turbidity is evaluated by measuring the transmission and scattering of light passing through the urine specimen. These analytical methods are identical to the methods used by the predicate Clinitek Atlas. The predicate ChemStrip Super UA uses reflectance spectroscopy for the measurement of all urine analyte species, including SG.

The AUTION Sticks 9EB multi-parameter test strips contain reactive pads impregnated with reagents formulated to react with a specific urine analyte. Each strip also contains a correction pad with no reagents for urine color determination. Like the proposed AUTION Sticks, the Clinitek Atlas reagent strips and the Chemstrip 10 S-UA test strips consist of reagent pads on a non-reactive plastic backing.

The mechanisms of action for the chemical reactions used for the determination of urinary analytes, including glucose and occult blood, are similar for the proposed and predicate test strips. The chemical constituents of the individual reagent formulations are similar for the proposed and predicate reagent pads, with minor differences in the choice of enzyme substrate and chromogens used for production of the colored endproduct.

7. PERFORMANCE TESTING

Several studies were conducted to evaluate the performance characteristics of the AUTION MAX Urinalysis System. A correlation study demonstrated excellent agreement when results from the AUTION MAX were compared to those from a commercially available automated urine analyzer. Additional studies for precision, carryover, and linearity demonstrated acceptable performance of the AUTION MAX System for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 8 2002

International Remote Imaging Systems, Inc.
c/o Cynthia J. M. Nolte, Ph.D., RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: k013783
Trade/Device Name: AUTION MAX™ AX-4280 URINALYSIS SYSTEM
Regulation Number: 21 CFR 862.2900, 862.1785, 862.1550, 862.1340, 862.1435, 864.6550, 862.1645, 862.1115, 862.1510, 862.2800, 864.7675
Regulation Name: Automated Urinalysis System, Urinary urobilinogen (nonquantitative) test system, Urinary pH (nonquantitative) test system, Urinary glucose (nonquantitative) test system, Ketones (nonquantitative) test system, Occult blood test, Urinary protein or albumin (nonquantitative) test system, Urinary bilirubin and its conjugates (nonquantitative) test system, Nitrite (nonquantitative) test system, Refractometer for clinical use, Leukocyte peroxidase test
Regulatory Class: Class I, II
Product Code: KQO, CDM, CEN, JIL, JIN, JIO, JIR, JJB, JMT, JRE, LJX
Dated: November 12, 2001
Received: November 14, 2001

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013783

Device Name: AUTION MAX™ AX-4280 Urinalysis System

Indications for Use:

The AUTION MAX AX-4280 Urinalysis System (AUTION MAX) is an automated urine analyzer intended for the in vitro measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, specific gravity, turbidity, and color. The AUTION MAX is intended for use only with AUTION Sticks 9EB multi-parameter test strips.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013783

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)